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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/868,442	07/24/2001	Samir S. Mitragotri	031852.0029	1231

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HUNTON & WILLIAMS
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EXAMINER

FOREMAN, JONATHAN M

ART UNIT	PAPER NUMBER
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3736

DATE MAILED: 08/15/2003

10

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/868,442

Applicant(s)

MITRAGOTRI ET AL.

Examiner

Jonathan ML Foreman

Art Unit

3736

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 May 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 72 - 119 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 72-76, 79-88, 90-92, 95-98 and 101-119 is/are rejected.
- 7) ☒ Claim(s) 77-79, 89, 93, 94, 99 and 100 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Figures 13 - 15 in Paper No. 9 is acknowledged.
2. Claims 1 - 71 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 9.

Information Disclosure Statement

The information disclosure statement filed 7/24/01 complies with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609. It has been placed in the application file, and the information referred to therein has been considered by the examiner as to the merits.

Specification

3. The disclosure is objected to because of the following informalities: There is no "Brief Description of the Drawings" for Figures 3A, 3B and Figures 12A - C.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claim 96 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
6. Claim 96 recites the limitation "said hydrophobic coating" in line 1. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

8. Claims 72 – 74, 82 – 85, 90, 97, 101, 103 – 116 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 5,722,397 to Eppstein.

In reference to claims 72 – 74, 79, 82 – 85, 90, 97, 101, 103 - 106, Eppstein discloses applicant's claimed invention including increasing a permeability level of an area of skin with ultrasound (Col. 4, lines 41 – 49); extracting a body fluid from the area of skin (Col. 4, line 49); collecting the body fluid (Col. 4, line 49); and sensing the presence of at least one analyte in the body fluid (Col. 4, lines 41 – 45). Eppstein discloses extracting a body fluid being selected from physical forces, chemical forces, vacuum, electrical forces, osmotic forces, diffusion forces, electro-magnetic forces, ultrasound forces, cavitation forces, mechanical forces, thermal forces, capillary forces, fluid circulation across the skin, electro-acoustic forces, magnetic forces, photo acoustic forces and any combination thereof (Col. 4, line 46 – Col. 5, line 3). The ultrasound is applied to create a result from pump body fluid and fluid components, activate gas bodies, producing cyclic impulse mechanical stress, create microstreaming, increase temperature and set up standing waves (Col. 5, lines 14 – 21). Eppstein discloses a plurality of ultrasound-producing devices having at least one different operating characteristic selected from frequency, intensity, and coupling media (Col. 5, lines 22 – 32). Collecting the body fluid comprises using one from the group of absorption, adsorption,

Art Unit: 3736

phase separation, mechanical, electrical, chemically induced, capillary forces and a combination thereof. The mechanical collection method comprises applying vacuum, pressure or acoustic forces. The sensing step senses the presence of at least one analyte by applying a sensing method selected from the group of electrochemical, optical, acoustical, biological, enzymatic technology and combinations thereof (Col. 17, lines 46 – 54). Eppstein discloses an output for a user interface having an alarm that indicates an abnormal analyte concentration (Col. 21, lines 10 – 18). The output additionally provides trend information and is downloadable (Col. 19, lines 7 – 13).

In regards to claims 107 – 116, Eppstein discloses applicant's claimed invention including an ultrasonic transducer (146); an extraction device; a collection device; and a sensing device (Col. 17, line 43 – Col. 18, line 16). A micro controller controls at least one of the transducer; the extraction device; the collection device; and the sensing device. Eppstein discloses a user output device controlled by the micro controller (Col. 18, line 17 – Col. 19, line 13). Eppstein discloses extracting a body fluid being selected from physical forces, chemical forces, vacuum, electrical forces, osmotic forces, diffusion forces, electro-magnetic forces, ultrasound forces, cavitation forces, mechanical forces, thermal forces, capillary forces, fluid circulation across the skin, electro-acoustic forces, magnetic forces, photo acoustic forces and any combination thereof (Col. 4, line 46 – Col. 5, line 3). Collecting the body fluid comprises using one from the group of absorption, adsorption, phase separation, mechanical, electrical, chemically induced, capillary forces and a combination thereof. The sensing step senses the presence of at least one analyte by applying a sensing method selected from the group of electrochemical, optical, acoustical, biological, enzymatic technology and combinations thereof. The output device provides information from the group of trend information, history information, operating information, and combinations thereof (Col. 21, lines 10 – 18). The information is downloadable to a computer (Col. 19, lines 7 – 13).

Claims 72 – 74, 80 - 82, 88, 90 - 92, 97, 98 and 102 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 5,947,921 to Johnson et al.

In reference to claims 72 – 74, 80 - 82, 88, 90 - 92, 97, 98 and 102, Johnson et al. discloses applicant's claimed invention including increasing a permeability level of an area of skin with ultrasound (Col. 1, lines 6 – 9); extracting a body fluid from the area of skin (Col. 3, lines 53 – 56); collecting the body fluid; and sensing the presence of at least one analyte in the body fluid. Johnson et al. discloses extracting a body fluid being selected from physical forces, chemical forces, vacuum, electrical forces, osmotic forces, diffusion forces, electro-magnetic forces, ultrasound forces, cavitation forces, mechanical forces, thermal forces, capillary forces, fluid circulation across the skin, electro-acoustic forces, magnetic forces, photo acoustic forces and any combination thereof (Col. 8, lines 6 – 14). The ultrasound is applied to create a result from pump body fluid and fluid components, activate gas bodies, producing cyclic impulse mechanical stress, create microstreaming, increase temperature and set up standing waves (Col. 4, lines 7 – 34). Johnson et al. discloses the electrical force being selected from iontophoretic, electro-osmotic, and electroporation (Col. 8, line 10). Thermal forces are created by a source selected from electric, chemical, ultrasonic, and optical energy sources. Collecting the body fluid comprises using one from the group of absorption into a gel, adsorption, phase separation, mechanical, electrical, chemically induced, capillary forces and a combination thereof (Col. 11, lines 7 – 14). The mechanical collection method comprises applying vacuum (Col. 9, lines 7 – 11), pressure or acoustic forces. Johnson et al. discloses applying a gel to the skin to encourage osmosis (Col. 11, lines 7 – 11). The electrical collection comprises moving a charged object from the skin to a collecting compartment using electrical forces (Col. 8, lines 17 – 62).

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claims 75 and 76 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,947,921 to Johnson et al. in view of U.S. Patent No. 6,283,926 to Cunningham et al.

In reference to claims 75 and 76, Johnson et al. discloses using a vacuum (Col. 9, lines 6 – 10). However, Johnson et al. fails to disclose the vacuum being applied continuously of discontinuously. Cunningham et al. teaches a body fluid obtaining device wherein vacuum is applied both continuously and discontinuously (Col. 10, lines 38 – 41). It would have been obvious to one having ordinary skill in the art at the time the invention was made to supply the vacuum as disclosed by Johnson et al. in either a continuous or discontinuous manner to obtain greater volumes of body fluid (Col. 10, lines 38 – 41).

11. Claims 86 and 87 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,947,921 to Johnson et al. in view of U.S. Patent No. 6,468,229 to Grace et al.

In reference to claims 86 and 87, Johnson et al. discloses using a pressure gradient to enhance the physical movement of liquid across the skin (Col. 9, lines 4 – 6), but fails to disclose using a tensioner having a cavity to collect the fluid therein. Grace et al. discloses a tensioner (Figures 2A – G) having a cavity (26) for the collection of fluid. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method as disclosed by Johnson et al. to include the steps of using a tensioner having a cavity to collect fluid therein as

Art Unit: 3736

taught by Grace et al. in order to increase the amounts of interstitial fluids that are collected (Col. 2, lines 25 – 30).

12. Claim 95 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,947,921 to Johnson et al. in view of U.S. Patent No. 6,503,198 to Aronowitz et al.

In reference to claim 95, Johnson et al. discloses the step of collecting the body fluid into a gel, but fails to disclose the gel being a hydrophobic coating applied to the skin prior to extracting a body fluid from the skin. Aronowitz et al. teaches applying a hydrophobic coating to the skin prior to fluid extraction from the skin (Col. 16, lines 16 – 46). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method as disclosed by Johnson et al. to include the step of applying a hydrophobic coating to the skin prior to fluid extraction as taught by Aronowitz et al. in order to enhance the permeation of the skin (Col. 16, lines 38 – 44).

13. Claims 117 - 119 rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,722,397 to Eppstein in view of U.S. Patent No. 5,947,921 to Johnson et al.

In reference to claims 117, 118 and 119, Eppstein discloses applicant's claimed method and apparatus including a transducer (238) for increasing the permeability of the skin (Col. 20, lines 54 – 57); an extraction device for extracting interstitial fluid from the skin; a collection device (234) for collecting the interstitial fluid; the collection device has a glucose sensitive reagent that changes a characteristic of the gel when glucose is present (Col. 19, lines 16 – 44; Col. 20, lines 51 – 52); and a monitoring device for monitoring the changes in the reagent (Col. 20, lines 58 – 60). However, Eppstein fails to disclose collecting the interstitial fluid in a gel. Johnson et al. teaches that one way to collect interstitial fluid is in a gel (Col. 11, lines 7 – 11). It would have been obvious to one

Art Unit: 3736

having ordinary skill in the art to collect the interstitial fluid in a gel as taught by Johnson et al. in order to measure the concentration of the glucose using a biosensor (Col. 11, lines 10 – 12).

Allowable Subject Matter

14. Claims 77 – 79, 89, 93, 94, 99 and 100 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. The prior art does not teach or suggest placing a material between the vacuum force and skin to maintain a surface configuration of the skin. Nor does the prior art teach or suggest using temperature sensitive polymers to extract body fluids. The prior art does not teach or suggest a phase separation method including isolating the body fluid with an appropriate density immiscible fluid. The prior art does not teach or suggest using a hydrophilic gel to collect body fluids or filling a capillary with a plurality of fibers to collect body fluid.

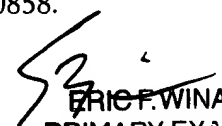
Conclusion

15. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. U.S. Patent No. 6,283,926 to Cunningham et al.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jonathan ML Foreman whose telephone number is (703)-305-5390. The examiner can normally be reached on Monday - Friday 8:00 am - 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max F Hindenburg can be reached on (703)308-3130. The fax phone numbers for the organization where this application or proceeding is assigned are (703)-308-0758 for regular communications and (703)-308-0758 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)-308-0858.


ERIC F. WINAKUR
PRIMARY EXAMINER

Application/Control Number: 09/868,442

Page 9

Art Unit: 3736

A handwritten signature in black ink, appearing to be the letters 'JMLF' with a stylized flourish at the end.

JMLF

August 11, 2003